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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,515	09/28/2001	Michael S. Kopreski	00-1312-C	5477

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EXAMINER
LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,515	Kopreski, M.	
	Examiner	Art Unit	
	Frank Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 21, 36, 37, and 40-53, drawn to a method for detecting tumor-derived or tumor-associated RNA in the plasma or serum fraction of blood (claims 1, 3, 5, 7, 9, 11 and 36), a method for detecting extracellular tumor-derived or tumor-associated RNA in a bodily fluid (claims 2, 4, 6, 8, 10, 12, and 37), a method for monitoring an animal or human for a malignant or premalignant disease (claim 21), a method for monitoring response to an anticancer therapy (claims 40 and 41), a diagnostic kit (claim 42-51), and a method for producing cDNA of epidermal growth factor by reverse transcription (claims 52 and 53), classified in class 435, subclass 91.2.

II. Claims 13-16 and 22, drawn to a method for identifying an animal or human having EGF, EGFr, her-2/neu, c-myc, or hnRNP A2/B1 expressing cells or tissue (claims 13-16), method for monitoring an animal or human for a malignant or premalignant disease (claim 22), classified in class 435, subclass 91.2.

III. Claims 17-20, drawn to a method for detecting or diagnosing a disease associated with expression of tumor-derived or tumor-associated RNA, classified in class 435, subclass 91.2.

IV. Claims 23-28 and 35, drawn to a method for selecting an animal or human with cancer for a therapy, classified in class 435, subclass 6.

V. Claims 29-34, 38, and 39, drawn to a method for a therapy, classified in class 435, subclass 91.2.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as extracellular tumor-derived or tumor-associated RNA of claim 2 is not required for Group II.

Groups I and III are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as diagnosing a disease associated with tumor-derived or tumor-associated RNA of claim 17 is not required for Group I.

Groups I and IV are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as selecting an animal or human for therapy of claim 23 is not required for Group I.

Groups I and V are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as therapy methods of claim 29 is not required for Group I.

Groups II and III are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as diagnosing a disease associated with tumor-derived or tumor-associated RNA of claim 17 is not required for Group II.

Groups II and IV are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as selecting an animal or human for therapy of claim 23 is not required for Group II.

Groups II and V are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as therapy methods of claim 29 is not required for Group II.

Groups III and IV are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as selecting an animal or human for therapy of claim 23 is not required for Group III.

Groups III and V are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as therapy methods of claim 29 is not required for Group III.

Groups IV and V are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as therapy methods of claim 29 is not required for Group IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Group I contains claims directed to the following patentably distinct species of the claimed invention:

(1) a kit for epidermal growth factor RNA (42 and 47)

(2) a kit for epidermal growth factor receptor RNA (43 and 48)

(3) a kit for her-2/neu RNA (44 and 49)

(4) a kit for c-myc RNA (45 and 50)

(5) a kit for herogeneous nuclear ribonucleoprotein A2/B1 (46 and 51)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are 1-12, 21, 36, 37, 40, 41, 52, and 53.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Group IV contains claims directed to the following patentably distinct species of the claimed invention:

(1) epidermal growth factor directed therapy (23 and 24)

(2) epidermal growth factor receptor directed therapy (25 and 26)

(3) her-2/neu directed therapy (27 and 28)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claim is claim 35.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG

94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
July 30, 2002